K073531

Summary of Safety and Effectiveness

FEB - 4 2008

Submitter: Michael Kvitnitsky
Accelerated Innovation, LLC
1033 US Highway 46, Suite A204
Clifton, NJ 07103

Date Prepared: December 10, 2007

Device: Accin™ Pedicle Screw System

Classification: 87MNI - Orthosis, Spinal Pedicle Fixation 21CFR 888.3070, Class II
87MNH – Orthosis, Spondylolisthesis Spinal Fixation, 21CFR 880.3070, Class II
87KWQ – Appliance, Fixation, Spinal Intervertebral Body, 21CFR 880.3060, Class II

Predicate Device: Vertebron PSS System – K033352, K043152, K051716 and K071376

Device Description: The Accin™ Pedicle System consists of titanium alloy rods, cannulated, multi-axial and standard screws, locking caps, and cross-connector components. The surgeon uses the components to make a construct for spinal fixation.

Intended Use: The Accin™ Pedicle Screw System components are intended for noncervical and nonpedicle anterolateral fixation of: degenerative disk disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis (grade 3 or 4); trauma (i.e.: fracture or dislocation); spinal stenosis; curvatures (i.e.: scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; failed previous fusion in skeletally mature patients.

The Accin™ Pedicle Screw System components are intended for non-cervical pedicle fixation of: Spondylolisthesis (grade 3 or 4); trauma (i.e.: fracture or dislocation); spinal stenosis; curvatures (i.e.: scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; failed previous fusion in skeletally mature patients.

Comparison to Predicates:
The Accin™ Pedicle Screw System consists of cannulated, multi-axial and standard screws, rods, cross-connectors, and locking caps manufactured from titanium alloy. The device is equivalent to the Vertebron PSS System, which also has the same components manufactured from the same materials.

Accin™ has determined that any differences in the proposed device will not impact the safety or effectiveness of the pedicle screw system for its intended use. Testing has shown that the proposed device meets the requirements of the current FDA Guidance document entitled "Spinal System 510(k)s" dated May 3, 2004, and that the proposed device is equivalent to the predicate device.

Synopsis of Test Methods and Results:
Tests were performed on the pedicle screw system. The testing was performed in accordance with ASTM F1717, Standard Test Methods for Static and Fatigue for Spinal Implant Constructs in a Vertebrectomy Model.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 4 2008

Accelerated Innovations, LLC
% Mr. Michael Kvitnitsky
Chief Operating Officer
1033 US Highway 46, Suite A204
Clifton, NJ 07103

Re: K073531
Trade/Device Name: Accin™ Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: II
Product Code: MNH, MNI, KWQ
Dated: December 7, 2007
Received: December 17, 2007

Dear Mr. Kvitnitsky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K073531

Device Name: Accin™ Pedicle Screw System

Indications for Use:

The Accin™ Pedicle Screw System components are intended for noncervical and nonpedicle anterolateral fixation of:

- Degenerative disk disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies);
- Spondylolisthesis (grade 3 or 4)
- Trauma (i.e.: fracture or dislocation)
- Spinal stenosis
- Curvatures (i.e.: scoliosis, kyphosis, and/or lordosis)
- Tumor
- Pseudoarthrosis
- Failed previous fusion.

The Accin™ Pedicle Screw System components are intended for non-cervical pedicle fixation of:

- Spondylolisthesis (grade 3 or 4)
- Trauma (i.e.: fracture or dislocation)
- Spinal stenosis
- Curvatures (i.e.: scoliosis, kyphosis, and/or lordosis)
- Tumor
- Pseudoarthrosis
- Failed previous fusion.

These components are single use only and are intended for use in skeletally mature patients.

Prescription Use X (Per 21 CFR 801.109) OR Over-The-Counter Use (Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073531